

**CLAIMS**

What is claimed is:

- 5           1.     A catheter system, comprising:  
              a mapping catheter comprising an open lumen and a mapping  
              arrangement provided at a distal end of the mapping catheter; and  
              a balloon catheter movably disposed within the open lumen of the  
              mapping catheter, the balloon catheter comprising:  
10                an open lumen dimensioned to receive a medical electrical lead;  
                  a balloon arrangement provided at a distal end of the balloon  
                  catheter and inflatable within the open lumen of the balloon catheter; and  
                  an inflation mechanism provided at a proximal end of the balloon  
                  catheter and fluidly coupled to the balloon arrangement facilitating inflation and  
15                deflation of the balloon arrangement, the balloon arrangement dimensioned to  
                  prevent movement of the lead upon inflation of the balloon arrangement, and to  
                  permit movement of the lead within the open lumen of the balloon catheter upon  
                  deflation of the balloon arrangement.
- 20           2.     The system of claim 1, wherein the balloon arrangement comprises at  
              least one annular balloon.
3.     The system of claim 1, wherein the balloon arrangement comprises at  
              least one fluted balloon.

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4. The system of claim 1, wherein the balloon catheter comprises an inflation lumen provided along a length of the balloon catheter, and the balloon arrangement comprises a unitary balloon fluidly coupled to the inflation mechanism via the inflation lumen.

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5. The system of claim 1, wherein the balloon catheter comprises a plurality of inflation lumens respectively provided along a length of the balloon catheter, and the balloon arrangement comprises a plurality of balloons each fluidly coupled to the inflation mechanism via the inflation lumens.

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6. The system of claim 1, wherein the balloon catheter is longitudinally displaceable and rotatable within the open lumen of the mapping catheter.

7. The system of claim 1, wherein the mapping arrangement comprises bipolar mapping electrodes.

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8. The system of claim 1, wherein the mapping arrangement comprises one or more accelerometers.

9. The system of claim 1, wherein the mapping arrangement comprises one or more acoustic sensors.

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10. The system of claim 1, wherein the lead comprises a fixation arrangement disposed at a distal tip of the lead, and the balloon arrangement engages the lead upon inflation of the balloon arrangement with a force that permits implanting of the fixation arrangement into cardiac tissue.

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11. The system of claim 1, wherein the lead comprises a helical fixation element disposed at a distal tip of the lead, and the balloon arrangement engages the lead upon inflation of the balloon arrangement with a force that permits rotational implanting of the helical fixation element into cardiac tissue.

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12. A lead delivery system, comprising:

a medical electrical lead;

a mapping catheter comprising an open lumen and a mapping arrangement provided at a distal end of the mapping catheter; and

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a balloon catheter movably disposed within the open lumen of the mapping catheter, the balloon catheter comprising:

an open lumen dimensioned to receive the lead;

a balloon arrangement provided at a distal end of the balloon catheter and inflatable within the open lumen of the balloon catheter; and

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an inflation mechanisms provided at a proximal end of the balloon catheter and fluidly coupled to the balloon arrangement facilitating inflation and deflation of the balloon arrangement, the balloon arrangement dimensioned to grasp the lead upon inflation of the balloon arrangement, and to permit movement of the lead within the open lumen of the balloon catheter upon deflation of the balloon arrangement.

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13. The system of claim 12, wherein the medical electrical lead comprises a pacing lead.

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14. The system of claim 12, wherein the medical electrical lead comprises a defibrillation lead.

15. The system of claim 12, wherein the medical electrical lead comprises a pacing lead comprising an open lumen.

16. The system of claim 15, wherein the open inner lumen is dimensioned  
5 to receive a guide wire or a finishing wire.

17. The system of claim 12, wherein the medical electrical lead comprises a lead having a closed lumen.

10 18. The system of claim 12, wherein the medical electrical lead comprises an active fixation mechanism.

19. The system of claim 12, wherein the medical electrical lead comprises a helical electrode.  
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20. The system of claim 12, wherein the medical electrical lead comprises fixation tines.

21. The system of claim 12, wherein the medical electrical lead comprises  
20 an extendable/retractable fixation element.

22. The system of claim 12, wherein the medical electrical lead comprises one or more spring-biased fixation elements.

25 23. The system of claim 12, wherein the medical electrical lead comprises a tip electrode configured for unipolar operation.

24. The system of claim 12, wherein the medical electrical lead comprises a tip electrode and a ring electrode configured for bipolar operation.

25. The system of claim 12, wherein the balloon arrangement comprises at least one annular balloon.

26. The system of claim 12, wherein the balloon arrangement comprises at least one fluted balloon.

27. The system of claim 12, wherein the balloon catheter comprises an inflation lumen provided along a length of the balloon catheter, and the balloon arrangement comprises a unitary balloon fluidly coupled to the inflation mechanism via the inflation lumen.

28. The system of claim 12, wherein the balloon catheter comprises a plurality of inflation lumens respectively provided along a length of the balloon catheter, and the balloon arrangement comprises a plurality of balloons each fluidly coupled to the inflation mechanism via the inflation lumens.

29. The system of claim 12, wherein the mapping arrangement comprises one or more accelerometers.

30. The system of claim 12, wherein the mapping arrangement comprises one or more acoustic sensors.

31. The system of claim 12, wherein mapping arrangement comprises bipolar mapping electrodes.

32. The system of claim 12, wherein the balloon catheter is longitudinally displaceable and rotatable within the open lumen of the mapping catheter.

5           33. The system of claim 12, wherein the lead comprises a fixation arrangement disposed at a distal tip of the lead, and the balloon arrangement engages the lead upon inflation of the balloon arrangement with a force that permits implanting of the fixation arrangement into cardiac tissue.

10           34. The system of claim 12, wherein the lead comprises a helical fixation element disposed at a distal tip of the lead, and the balloon arrangement engages the lead upon inflation of the balloon arrangement with a force that permits rotational implanting of the helical fixation element into cardiac tissue.

15           35. A method of delivering a medical electrical lead, comprising:  
              advancing a mapping catheter into a cardiac structure via an access vessel;  
              mapping, using the mapping catheter, the cardiac structure to locate an appropriate implant site;  
20           inflatably holding the lead within a balloon catheter such that an electrode of the lead extends beyond a distal tip of the balloon catheter;  
              advancing the balloon catheter through the mapping catheter so that the electrode contacts the implant site;  
              manipulating a proximal end of the balloon catheter to implant the  
25           electrode into cardiac tissue at the implant site; and  
              removing the balloon and mapping catheters.

36. The method of claim 35, wherein removing the balloon and mapping catheters comprises:

depressurizing the balloon catheter to permit relative movement between the balloon catheter and the lead;

5 retracting the balloon catheter in a proximal direction to remove the balloon catheter from the mapping catheter; and

removing the mapping catheter from the cardiac structure and the access vessel.

10 37. The method of claim 35, wherein manipulating the proximal end of the balloon catheter comprises rotatably manipulating the proximal end of the balloon catheter.

15 38. The method of claim 35, wherein manipulating the proximal end of the balloon catheter comprises longitudinally manipulating the proximal end of the balloon catheter.

20 39. The method of claim 35, wherein manipulating the proximal end of the balloon catheter comprises increasing pressurization of the balloon catheter when implanting the electrode into the cardiac tissue.

25 40. The method of claim 35, wherein manipulating the proximal end of the balloon catheter comprises rotating the proximal end of the balloon catheter and increasing pressurization of the balloon catheter when rotatably implanting the electrode into the cardiac tissue.

41. The method of claim 35, wherein inflatably holding the lead further comprises inflating one or more inflation balloons disposed at a distal end of the balloon catheter such that the one or more inflation balloons forceably engage the lead.

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42. The method of claim 35, wherein inflatably holding the lead further comprises advancing the lead through the balloon catheter until the electrode extends beyond the distal tip of the balloon catheter prior to advancing the balloon catheter through the mapping catheter.

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43. The method of claim 35, wherein mapping the cardiac structure comprises mapping a plurality of cardiac structure locations until electrical parameters indicate that the appropriate implant site has been located.

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44. The method of claim 35, further comprising verifying electrical performance of the implanted lead and repositioning the electrode in the cardiac structure if a nominal electrical performance level is not achieved.

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45. A lead delivery system for facilitating implantation of a lead electrode into cardiac tissue, comprising:

a mapping catheter comprising an open lumen, a proximal end, and a distal end provided with one or more mapping electrodes; and

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an inner catheter movably disposed within the open lumen of the mapping catheter, the inner catheter comprising an open lumen, a proximal end, a distal end, a grasping mechanism disposed within the open lumen at the distal end of the inner catheter, and an activation mechanism provided at the proximal end of the inner catheter, the open lumen of the inner catheter dimensioned to receive a



lead and to restrict movement of the lead's distal end at the inner catheter's distal end in response to activation of the grasping mechanism.

5       46.    The lead delivery system of claim 45, wherein the grasping mechanism comprises one or more balloons adapted to inflatably grasp the lead.

10       47.    The lead delivery system of claim 45, wherein the inner catheter is longitudinally displaceable and rotatable within the open lumen of the mapping catheter.

10       48.    The lead delivery system of claim 45, wherein the mapping arrangement comprises bipolar mapping electrodes.

15       49.    The lead delivery system of claim 45, wherein the mapping arrangement comprises one or more accelerometers or one or more acoustic sensors.

20       50.    A method of delivering a medical electrical lead, comprising:  
          advancing a mapping catheter into a cardiac structure via an access vessel;  
          mapping, using the mapping catheter, the cardiac structure to locate an appropriate implant site;  
          inflatably holding a lead within the mapping catheter such that an electrode of the lead extends beyond a distal tip of the mapping catheter;  
25       manipulating a proximal end of the lead to implant the electrode into cardiac tissue at the implant site; and  
          removing the mapping catheter.

51. The method of claim 50, wherein mapping the cardiac structure comprises mapping a plurality of cardiac structure locations until electrical parameters indicate that the appropriate implant site has been located.

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52. The method of claim 50, further comprising rotatably implanting the electrode into the cardiac tissue.

53. The method of claim 50, further comprising fixing the electrode into the cardiac tissue using a helical fixation element.

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54. The method of claim 50, further comprising fixing the electrode into the cardiac tissue using an extendable/retractable fixation element.

55. The method of claim 50, further comprising fixing the electrode into the cardiac tissue using one or more tines for fixation.

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56. The method of claim 50, further comprising fixing the electrode into the cardiac tissue using a spring-biased fixation element.

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